



The Investigator as the Custodian of the Data Chain

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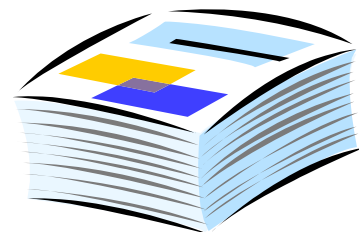


Agenda

- The investigator as the custodian of the data chain.



Data Chain



Clinical Trial Data supports safe and efficacious
medications for patients

■ ■ ■ What does good look like

- A relentless attention to detail and an impeccable ability to:
 - Follow **GCP**
 - Carry out the **protocol precisely** as written
- An insatiable passion for
 - **accurate**,
 - **complete**, and
 - **timely** documentation.

■ ■ ■ Following GCP and regulations

- **Patient safety**
 - Ensure IRB review and continuous approval of protocol and consent
 - Obtain consent prior to any protocol procedures
 - Report all adverse events
- **Data Integrity**
 - Create and maintain accurate source document
 - Maintain study documentation and medical records
 - Maintain investigational product disposition records
- **Protocol Adherence**
 - Inclusion/Exclusion
 - Conduct required procedures
 - Administer investigational product per protocol



Carry out protocol as written

- **Plan**

- Ensure study is consistent with your practice
- Ensure adequate site infrastructure
 - e.g. SOPs
- Develop checklists

- **Improve**

- Identify errors and put corrective and *preventive* actions in place

- **Control**

- Provide study oversight
- Monitor performance



Accurate and Complete Data

- **Accurate**

- Data points in CRF must be substantiated by source documents
 - Subject diaries
 - Lab reports
 - Medical record (including electronic)
 - Worksheets

- **Complete**

- Solicit information about AE's from patients and *report* them
- Avoid “Lost to Follow-Up”



Timely Data

- **Enter data at time of visit or other event**
 - Higher likelihood of accuracy and completeness
 - Minimize lag between when information is known and available to sponsor
 - Prompt data entry allows sponsor to detect safety signals as soon as possible to better protect patients